08/894548

88 Rec'd PCT/PTO 21 AUG 1997

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In re patent application of:)
)
Yimin Qin et al.)
)
Serial No. 08/_____)
)
Filed August 21, 1997)
)
WOUND DRESSING)

Before the Examiner

Group Art Unit _____

August 21, 1997

RECEIVED
16 SEP 1997
Legal Staff
International Division

Attention: Office of Petitions
Assistant Commissioner for Patents
Box DAC
Washington, D.C. 20231

PETITION UNDER 37 C.F.R. §1.137(b) FOR REVIVAL OF AN UNINTENTIONALLY ABANDONED APPLICATION

The above-identified patent application became abandoned for failure to submit the United States national stage application of International Patent Application No. PCT/GB95/02535 by the deadline of April 27, 1997. The abandonment date of this application is therefore April 28, 1997, and this Petition is being submitted less than one year from the abandonment date.

Applicant hereby petitions for revival of this application. The delay caused by the abandonment of the application was unintentional. Enclosed herewith is the required petition surcharge in the amount of $645.00 for a small entity pursuant to 37 C.F.R. §1.17(m). Also enclosed is

12/09/1997 WCLAYBRO 00000008 08894548
01 FC:254 65.00 CH

08/27/1997 WCLAYBRO 00000052 08894548
03 FC:241 645.00 OP

"Express Mail" label number EM221809479US
Date of Deposit August 21, 1997
I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37CFR § 1.10 on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Thomas Q. Henry
(Reg. No. 28,309)
Signature of person mailing paper or fee

a complete submission for the United States national stage of International Patent Application No. PCT/GB95/02535.

Consideration of this Petition and revival of the subject application is respectfully requested.

Respectfully submitted,

By ______________________

Thomas Q. Henry
Reg. No. 28,309
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FORM PTO-1390 (REV 10-96) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTORNEY'S DOCKET NUMBER

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

09 Rec'd PCT/PTO 21 AUG 1997

U.S. APPLICATION NO. (If known, see 37 CFR 1.5) 08/894548

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/GB95/02535	27 October 1995	27 October 1994

TITLE OF INVENTION
WOUND DRESSING

APPLICANT(S) FOR DO/EO/US
Yimin Qin and Denis Keith Gilding

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. ☒ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2)) Filed 15 May 1996
   a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau).
   b. ☒ has been transmitted by the International Bureau.
   c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
   a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
   b. ☒ have been transmitted by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d. ☐ have not been made and will not be made.
8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 16. below concern document(s) or information included:

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☒ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A FIRST preliminary amendment.
    ☐ A SECOND or SUBSEQUENT preliminary amendment.
14. ☐ A substitute specification.
15. ☐ A change of power of attorney and/or address letter.
16. ☒ Other items or information:

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Thomas Henry
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Signature of person mailing paper or fee

International Publication
International Preliminary Examination Report
Verified Statement Claiming Small Entity Status-Independent Inventor
Verified Statement Claiming Small Entity Status-Small Business Concern
Assignment with Recordation Form Coversheet
Petition Under 37 CFR 1.137(b) For Revival of an Unintentionally Abandoned Application with $645.00 surcharge for a small entity pursuant to 37 CFR 1.17(m).

9676Q

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of:	
Yimin Qin et al.	Before the Examiner
Serial No. 08/_____	Group Art Unit _____
Filed August 21, 1997	August 21, 1997
WOUND DRESSING	

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Please enter the following preliminary amendment in the above-identified patent application.

In the Claims:

Please cancel claims 1-18.

Please add the following new claims:

--19. A wound dressing comprises in combination

(i) a first wound contact layer which preferably has a positive effect on the healing of the wound,

(ii) a second layer of greater hydrophilicity than the first layer, and

(iii) a breathable film having an increased MVTR capability in the presence of liquid water as compared to moisture vapour alone.

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Thomas Henry
Thomas Q. Henry (Reg.No.28,309) Signature of person mailing paper or fee

20. A dressing as claimed in claim 19 wherein the hydrophilicity of layer (ii) is at least twice that of layer (i).

21. A dressing as claimed in claim 20 wherein the hydrophilicity of layer (ii) is 3 to 5 times that of layer (i).

22. A dressing as claimed in claim 19 wherein layer (i) has a thickness of 50 to 1,000 microns.

23. A dressing as claimed in claim 19 wherein layer (i) is one which provides for clotting via agglutination of red cells.

24. A dressing as claimed in claim 19 wherein the layer (i) is one which is capable of debriding the wound.

25. A dressing as claimed in claim 19 wherein layer (i) delivers a component to the wound.

26. A dressing as claimed in claim 19 wherein layer (i) comprises calcium alginate, zinc alginate, silver alginate, chitosan, pectin, silver N,O-carboxymethyl chitosan, silver O-carboxymethyl chitosan or a dehydrated hydrogel.

27. A dressing as claimed in claim 19 wherein layer (ii) is a woven, non-woven or knitted fibrous material.

28. A dressing as claimed in claim 19 wherein layer (ii) has a thickness of 1,000 to 5,000 microns.

29. A dressing as claimed in claim 19 wherein layer (ii) is a felt comprised of sodium alginate/calcium alginate, sodium calcium carboxymethyl cellulose, sodium zinc carboxymethyl cellulose, sodium calcium polyacrylate or sodium calcium carregeenin.

30. A dressing as claimed in claim 19 wherein the film has an MVTR in the presence of moisture vapour alone of 2,000 to 2,500 g m^{-2} $24hr^{-1}$.

31. A dressing as claimed in claim 19 wherein the film has an MVTR in the presence of liquid water of 6,000 to 30,000 g m^{-2} $24hr^{-1}$.

32. A dressing as claimed in claim 19 wherein the film has a thickness of 30-70 microns.

33. A dressing as claimed in claim 19 wherein the film is of a polyurethane.

34. A dressing as claimed in claim 19 wherein an adhesive is provided on the film for bonding the latter to skin around the wound.

35. A dressing as claimed in claim 34 wherein the adhesive is a hydroactive adhesive.

36. A dressing as claimed in claim 35 wherein the adhesive is one which, as a continous layer having a thickness of 20 microns, has an MVTR of 15,000 g m^{-2} $24hr^{-1}$.--

Remarks

Consideration of the above-identified patent application, as amended is respectfully requested.

Respectfully submitted,

By _____

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08/894548
PCT/GB95/02535
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WOUND DRESSING

The present invention relates to wound dressings.

For the treatment of many types of wounds, particularly medium to highly exuding wounds (e.g. 2nd and 3rd degree burns, decubitus ulcers and leg ulcers) it is necessary to ensure that bulk exudate is removed from the wound and peripheral skin to reduce or eliminate maceration. Prior art dressings have not always proved satisfactory in venting the large amount of exudate present in a wound. As such, the dressing becomes saturated and this results in maceration and excoriation. Additionally, the dressing may require to be changed relatively frequently and this is a labour intensive operation.

According to the present invention there is provided a wound dressing provided in combination

(i) a first wound contact layer which preferably has a positive effect on the healing of the wound, and

(ii) a second layer of greater hydrophilicity than the first layer.

Layer (i) is designed to provide a positive action in assisting healing of the wound and may take various forms (as described later) depending on the type of wound to be treated. The provision of layer (ii) (which is of greater hydrophilicity than layer (i) ensures that exudate present in layer (i) may pass into layer (ii) so as to increase the time before layer (i) becomes saturated. Preferably the hydrophilicity of layer (ii) is at least twice, and more preferably 3 to 5 times, that of layer (i).

Layer (i) (i.e. the wound contact layer) will generally be relatively thin (e.g. 50-1000 microns) and may be such as interact positively with the wound to assist healing thereof. Thus, for example, layer (i) may be one which provides for clotting via agglutination of red cells. Alternatively, the layer may be one which is capable of debriding the wound. A further possibility is for the layer to be one which delivers a component to the wound, e.g. an ion, drug, or anti-microbial agent. Examples of the materials which may be used for layer (i) are as follows:

(a) calcium alginate which will provide calcium ions for haemostasis;

(b) zinc alginate to deliver zinc ions into the wound to assist healing;

(c) silver alginate to deliver silver ions as powerful anti-microbial agents to infected wounds;

(d) chitosan to provide haemoglutination (i.e. clotting by gelation of red cells leaving the intrinsic and extrinsic clotting cascade intact). Chitosan also appears to have some beneficial effects on contact allergies and anti-microbial activity by stimulating the oxidative attack of white cells. Chitosan has also been reported to assist healing and reduce scarring;

(e) pectin for stimulating autolysis and wound debridement. The pectin may be provided, for example, as pectin/carboxymethyl cellulose/alginate or pectin/alginate;

(f) silver N,O-carboxymethyl chitosan or silver O-carboxymethyl chitosan;

(g) a gauze material prepared as described in our earlier U.K. Patent Application No. 9415828 and incorporating silver ions for delivery to the wound;

(h) a dehydrated hydrogel, e.g. of alginate or chitosan, which is of high integrity when it picks up water.

Layer (i) may be provided as a woven, non-woven or knitted material or as a gel. The layer may be in the form of a "rope" for deep cavities or an amorphous gel for sinuses.

Various species may be incorporated in layer (i) for delivery to the wound, e.g.

simple anti microbial agents (e.g. Zn^{2+} and Ag^{+}) and metal ions which are enzyme cofactors

enzymes such as collogenase and metallo proteases such as plasmin or plasminogen which can be dosed into layer (i) to be released into the wound during healing to aid fibrinolysis and reduce scar formation

drugs, such as anti-inflammatories etc., for dermatological application.

Layer (i) will also capture proteins and growth factors from the wound, initially by adsorption and as this layer hydrates later in the healing process these proteins and growth factors will be delivered back to the healing wound.

Layer (ii) is preferably also of a woven, non-woven or knitted fibrous material, e.g. a felt.

Layer (ii) will generally have a thickness of 1000 to 5000 microns, preferably 1000 to 2500 microns and may comprise

(a) sodium alginate/calcium alginate felt (e.g. containing 20-60% sodium);

(b) a sodium calcium carboxymethyl cellulose felt;

(c) a sodium zinc carboxymethyl cellulose felt;

(d) a sodium calcium polyacrylate felt; or

(e) a sodium calcium carrageenin felt.

(f) an alginate/CMC felt.

(g) carboxymethyl cellulose (CMC) felt; or

(h) N,O-carboxymethyl chitosan (NOCC) felt.

The sodium in the above materials may be replaced by potassium.

One particular example of wound dressing in accordance with the invention comprises chitosan as layer (i) and an alginate or alginate/CMC felt as layer (ii).

As explained above, layer (ii) is of greater hydrophilicity than layer (i). The requisite hydrophilicity (rate of exudate absorption) for layer (ii) may be obtained by mixing fibres of varying sodium/calcium ratios (for felts (a), (b), (d), and (e)) and by mixing fibres of varying sodium/zinc ratios (for felt (e)). The absolute capacity of the felt for absorbing exudate may be varied by mixing fibres of varying hydrophilicity. For example the absorption capacity of felts made from CMC, polyacrylate or NOCC, all of which are powerfully hydrophilic, may be lowered by the incorporation of alginate fibres. Alternatively, materials of the requisite absorption capability may comprise alginates co-spun with other polymeric materials as disclosed in our copending U.K. Patent Application No. 9419572.

As an alternative to layers (i) and (ii) both being non-woven, it is possible for layers (i) and/or (ii) to be of other types of material (provided that layer (ii) is more hydrophilic than layer (i)). Examples of such alternative constructions are as follows.

(1) Layer (i) is a non-woven felt and layer (ii) is a hydrogel. An example of such a dressing is one comprising a non-woven felt of chitosan (as layer (i) with a NOCC hydrated hydrogel (as layer (ii)). In such a dressing, the chitosan provides haemostatic and anti-microbial properties and the highly absorbing NOCC provides the exudate handling properties. The exclusive nature of the gel ensures that growth factors and other proteins from the wound remain in layer (i) (i.e. the chitosan layer) for ultimate delivery back to the wound. The dressing is suitable for donor sites and 2nd and 3rd degree burns. Obviously a NOCC hydrated hydrogel may be used in conjunction with other (less hydrophilic) materials as layer (i).

(2) Layer (i) may be comprised of spun hydrocolloid including a mixture of components to produce a product which is a cross between an alginate and a hydrocolloid. Thus, for example, it is possible to spin hydrocolloids from solutions of alginate, gelatin, pectin, and CMC, e.g. in the following amounts.

Alginate	Gelatin	Pectin	CMC
45	10	25	20
35	10	35	20

In this case, the layer (ii) may for example be a material as described in our aforementioned copending U.K. Patent Application No. 9415828, a relatively high sodium or potassium (e.g. 20-60%) calcium alginate, carboxymethyl cellulose or polyacrylic acid/alginate.

Layers (i) and (ii) may be joined together, e.g. by needle punching, or may be applied separately to the wound.

In a highly preferred embodiment of the invention, the dressing comprising layers (i) and (ii) is associated with a breathable film which is of increased MVTR capability in the presence of liquid water as compared to moisture vapour only. MVTR in the presence of liquid water may be measured by ASTM E96BW whereas MVTR in the presence of moisture vapour alone may be measured by ASTM E96B (water method). Preferably the value of the breathability in the presence of liquid water is at least twice and preferably at least three times that in the presence of moisture vapour alone. The value may be up to 30 or 40 times that for moisture vapour alone. Typically the film will be of a material which has an MVTR in the presence of moisture vapour alone (ASTM E96B) of 2,000 to 2,500 g m^{-2} $24hr^{-1}$ and an MVTR in the presence of liquid water (ASTM E96BW) in the range 6,000 to 30,000 g m^{-2} $24hr^{-1}$ (e.g. 6,00 to 10,000 g m^{-2} $24hr^{-1}$). Typically the film will have a thickness of 30-70 microns more preferably 40-60 microns, e.g. about 50 microns.

The film may for example be of polyurethane. Suitable films are available from Innovative Technologies Limited under the designations IT325, IT425 and IT625.

An adhesive will be provided on the film for bonding the latter two the skin around the wound. The adhesive is preferably a hydroactive adhesive most preferably one which, as a continuous layer having a thickness of 20 microns, has an MVTR of 15,000 g m^{-2} $24hr^{-1}$ using ASTM E96B. Preferably the combination of the adhesive and film is such as to provide an MVTR of 6,000 to 10,000 g m^{-2} $24hr^{-1}$. An example of a

suitable adhesive is a hydroactive adhesive available from Innovative Technologies under the designation ITHA.

The hydroactive adhesive may be provided as a continuous layer on the film. The coating thickness is preferably in the range 15 to 25 microns e.g. about 20 microns.

Alternatively the adhesive may be a pressure sensitive adhesive provided as a cross-pattern to achieve 20-50% area coverage and to achieve similar MVTRs for the combination of adhesive and film of 6,000 to 10,000 g m^{-2} $24hr^{-1}$.

When the dressing is applied to a wound, the film will generally simply be laid over the combination of layers (i) and (ii).

In use of the dressing comprising such a film, exudate from the wound will initially be absorbed into layer (ii) and will pass therethrough until it comes into contact with the film. The breathability of the film is increased in contact with the liquid present in layer (ii), the increase being dependant on the amount of exudate present in layer (ii) (a greater amount of exudate in layer (ii) producing a greater increase in the breathability of the film). Moisture is therefore able to vent from layer (ii) via the film at a rate which is greater than the MVTR of layer (ii) which is therefore prevented from becoming saturated.

As the wound begins to dry-up during the healing process, the MVTR of the film decreases so that layer (ii) remains moist and does not dry out, thus facilitating healing.

The invention will be illustrated with reference to the following non-limiting Examples.

Example 1

A non-woven felt made of chitosan fibres and a non-woven felt of a calcium/sodium alginate were needled together to form a two-layer dressing. The chitosan felt provides a wound contacting layer which promotes healing of the wound and also provides antimicrobial properties for the dressing. The calcium/sodium alginate felt has a high absorption capacity.

This combined dressing has the wound healing properties of the chitosan felt and the absorbency of the calcium/sodium alginate felt. By drawing the fluid away from the wound surface, the wound is kept in a relatively dry condition thereby eliminating build up of wound exudate and remove skin maceration.

Example 2

A non-woven felt of calcium alginate fibres and a non-woven felt of a calcium/sodium alginate were needled together to form a two-layer dressing. The calcium/sodium alginate contained a minimum of 10% of sodium so as to render it more absorbent than the pure calcium alginate felt.

The calcium alginate fibre was a high M fibre which gels more easily than the high G fibre. On application to a wound, the calcium alginate fibre gels to form a moist protective layer whilst excessive fluid is taken up by the calcium/sodium alginate. The wound is therefore kept in a moist healing environment whilst maceration of healthy

skin is prevented by the removal of excessive fluid to the calcium/sodium alginate fibre (the upper layer).

CLAIMS

1. A wound dressing comprises in combination

(i) a first wound contact layer which preferably has a positive effect on the healing of the wound,

(ii) a second layer of greater hydrophilicity than the first layer, and

(iii) a breathable film having an increased MVTR capability in the presence of liquid water as compared to moisture vapour alone.

2. A dressing as claimed in claim 1 wherein the hydrophilicity of layer (ii) is at least twice that of layer (i).

3. A dressing as claimed in claim 2 wherein the hydrophilicity of layer (ii) is 3 to 5 times that of layer (i).

4. A dressing as claimed in any one of claims 1 to 3 wherein layer (i) has a thickness of 50 to 1,000 microns.

5. A dressing as claimed in any one of claims 1 to 4 wherein layer (i) is one which provides for clotting via agglutination of red cells.

6. A dressing as claimed in any one of claims 1 to 4 wherein the layer (i) is one which is capable of debriding the wound.

7. A dressing as claimed in any one of claims 1 to 4 wherein layer (i) delivers a component to the wound.

8. A dressing as claimed in any one of claims 1 to 4 wherein layer (i) comprises calcium alginate, zinc alginate, silver alginate, chitosan, pectin, silver N,O-carboxymethyl chitosan, silver O-carboxymethyl chitosan or a dehydrated hydrogel.

9. A dressing as claimed in any one of claims 1 to 8 wherein layer (ii) is a woven, non-woven or knitted fibrous material.

10. A dressing as claimed in any one of claims 1 to 9 wherein layer (ii) has a thickness of 1,000 to 5,000 microns.

11. A dressing as claimed in any one of claims 1 to 10 wherein layer (ii) is a felt comprised of sodium alginate/calcium alginate, sodium calcium carboxymethyl cellulose, sodium zinc carboxymethyl cellulose, sodium calcium polyacrylate or sodium calcium carrageenin.

12. A dressing as claimed in any one of claims 1 to 11 wherein the film has an MVTR in the presence of moisture vapour alone of 2,000 to 2,500 g $m^{-2}24hr^{-1}$.

13. A dressing as claimed in any one of claims 1 to 12 wherein the film has an MVTR in the presence of liquid water of 6,000 to 30,000 g $m^{-2}24hr^{-1}$.

14. A dressing as claimed in any one of claims 1 to 13 wherein the film has a thickness of 30-70 microns.

15. A dressing as claimed in any one of claims 1 to 14 wherein the film is of a polyurethane.

16. A dressing as claimed in any one of claims 1 to 15 wherein an adhesive is provided on the film for bonding the latter to skin around the wound.

17. A dressing as claimed in claim 16 wherein the adhesive is a hydroactive adhesive.

18. A dressing as claimed in claim 17 wherein the adhesive is one which, as a continuous layer having a thickness of 20 microns, has an MVTR of 15,000 g $m^{-2}24hr^{-1}$.

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(54) Title: WOUND DRESSING

(57) Abstract

A wound dressing comprises in combination (i) a first wound contact layer which preferably has a positive effect on the healing of the wound, and (ii) a second layer of greater hydrophilicity than the first layer.

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YIMIN QIN
Applicant or Patentee: DENIS KEITH GILDING Attorney's Docket No.. 7250-3 (Qin)
Serial or Patent No:
Filed or Issued: Filed August 21, 1997
For: WOUND DRESSING

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS (37 CFR 1.9 (f) and 1.27 (b)) - INDEPENDENT INVENTOR

As a below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 CFR 1.9 (c) for purposes of paying reduced fees under section 41 (a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention entitled WOUND DRESSING described in.

[X] the specification filed herewith
[ ] application serial no. _____, filed _____
[ ] patent no. _____, issued _____

I have not assigned, granted, conveyed or licensed and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 CFR 1.9 (c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9 (d) or a nonprofit organization under 37 CFR 1.9 (e).

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*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

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FULL NAME _____
ADDRESS _____
( ) INDIVIDUAL ( ) SMALL BUSINESS CONCERN ( ) NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28 (b)).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

YIMIN QIN	DENIS KEITH GILDING	
NAME OF INVENTOR	NAME OF INVENTOR	NAME OF INVENTOR
Signature of Inventor	Signature of Inventor	Signature of Inventor
Date	Date	Date

Yimin Qin Sign here 14.7.97. Keith Gilding Sign here 14/07/97

Form PTO-FB-A410 (8-83)

YIMIN QIN
Applicant or Patentee: DENIS KEITH GILDING Case Docket No. 7250-3 (Qin)
Serial or Patent No:
Filed or Issued: Filed August 21, 1997
For: WOUND DRESSING

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS (37 CFR 1.9 (f) and 1.27 (b)) - SMALL BUSINESS CONCERN

I hereby declare that I am

( ) the owner of the small business concern identified below.
(X) an official of the small business concern empowered to act on behalf of the concern identified below.

NAME OF CONCERN INNOVATIVE TECHNOLOGIES LIMITED
ADDRESS OF CONCERN ROAD THREE, WINSFORD INDUSTRIAL ESTATE, WINSFORD, CHESHIRE, CW7 3PD, UNITED KINGDOM

I hereby declare that the above identified small business concern qualifies as a small business concern as defined in 13 CFR 121.3-18.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention entitled WOUND DRESSING by inventor(s) YIMIN QIN and DENIS KEITH GILDING described in

(X) the specification filed herewith
( ) application serial no. _____, filed _____
( ) patent no. _____, issued _____

If the right held by the above identified small business concern is not exclusive, each individual, concern or organization having rights to the invention is listed below and no rights to the invention are held by any person, other than the inventor, who could not qualify as a small business concern under 37 CFR 1.9 (d) or by any concern which would not qualify as a small business concern under 37 CFR 1.9 (d) or a nonprofit organization under 37 CFR 1.9 (e).

FULL NAME _____
ADDRESS _____
( ) INDIVIDUAL ( ) SMALL BUSINESS CONCERN ( ) NONPROFIT ORGANIZATION

FULL NAME _____
ADDRESS _____
( ) INDIVIDUAL ( ) SMALL BUSINESS CONCERN ( ) NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28 (b)).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING D. K. Gilding
TITLE OF PERSON OTHER THAN OWNER CEO
ADDRESS OF PERSON SIGNING Nepentle, Winsford Road, Wolbenhall, Winsford, Cheshire, CW7 4DL, UK
SIGNATURE D K Gilding DATE 13.7.97

Signed by an Authorised officer of IT

Combined Declaration For Patent Application and Power of Attorney (Continued)
(Includes Reference to PCT International Applications)

ATTORNEY'S DOCKET NUMBER: 7250-3 (Qin)

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowlege the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56 which occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application:

PRIOR U.S. APPLICATIONS OR PCT INTERNATIONAL APPLICATIONS DESIGNATING THE U.S. FOR BENEFIT UNDER 35 U.S.C. 120:

U S APPLICATIONS		STATUS (Check one)		
U S APPLICATION NUMBER	U S FILING DATE	PATENTED	PENDING	ABANDONED
PCT APPLICATIONS DESIGNATING THE U.S				
PCT APPLICATION NO	PCT FILING DATE	U S SERIAL NUMBERS ASSIGNED (if any)		
PCT/GB95/02535	27 Oct 1995			X

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. (List name and registration number)
WOODARD EMHARDT NAUGHTON MORIARTY & McNETT
111 Monument Circle, Suite 3700
Indianapolis, IN 46204 (see attached listing)

Send Correspondence to:
Thomas Q. Henry, Esq.
WOODARD EMHARDT NAUGHTON MORIARTY & McNETT
111 Monument Circle, Suite 3700
Indianapolis, IN 46204

Direct Telephone Calls to: (name and telephone number)
Thomas Q. Henry
(317) 634-3456

201	FULL NAME OF INVENTOR	FAMILY NAME: QIN	FIRST GIVEN NAME: YIMIN	SECOND GIVEN NAME:
	RESIDENCE & CITIZENSHIP	CITY: NORTHWICH	STATE OR FOREIGN COUNTRY: UNITED KINGDOM GBX	COUNTRY OF CITIZENSHIP: CHINA
	POST OFFICE ADDRESS	POST OFFICE ADDRESS: 123 VICTORIA ROAD	CITY: NORTHWICH, CHESHIRE	STATE & ZIP CODE/COUNTRY: CW9 5RQ, U.K.
202	FULL NAME OF INVENTOR	FAMILY NAME: GILDING	FIRST GIVEN NAME: DENIS	SECOND GIVEN NAME: KEITH
	RESIDENCE & CITIZENSHIP	CITY: WINSFORD	STATE OR FOREIGN COUNTRY: UNITED KINGDOM GBX	COUNTRY OF CITIZENSHIP: UNITED KINGDOM
	POST OFFICE ADDRESS	POST OFFICE ADDRESS: WINSFORD ROAD	CITY: WETTENHALL, WINSFORD, CHESHIRE	STATE & ZIP CODE/COUNTRY: CW7 4DL, U.K.
203	FULL NAME OF INVENTOR	FAMILY NAME:	FIRST GIVEN NAME:	SECOND GIVEN NAME:
	RESIDENCE & CITIZENSHIP	CITY:	STATE OR FOREIGN COUNTRY:	COUNTRY OF CITIZENSHIP:
	POST OFFICE ADDRESS	POST OFFICE ADDRESS:	CITY:	STATE & ZIP CODE/COUNTRY:

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Keith Gilding sign here

SIGNATURE OF INVENTOR 201	SIGNATURE OF INVENTOR 202	SIGNATURE OF INVENTOR 203
DATE: 14/07/97	DATE: 11/07/97	DATE:

POWER OF ATTORNEY

Harold R. Woodard, No. 16,214; C. David Emhardt, No. 18,483; Joseph A. Naughton, Jr., No. 19,814; John V. Moriarty, No. 26,207; John C. McNett, No. 25,533; Thomas Q. Henry, No. 28,309; James M. Durlacher, No. 28,840; Charles R. Reeves, No. 28,750; Vincent O. Wagner, No. 29,596; Steve Zlatos, No. 30,123; Spiro Bereveskos, No. 30,821; William F. Bahret, No. 31,087; Clifford W. Browning, No. 32,201; R. Randall Frisk, No. 32,221; Daniel J. Lueders, No. 32,581; Michael D. Beck, No. 32,722; Kenneth A. Gandy, No. 33,386; Timothy N. Thomas, No. 35,714; Kerry P. Sisselman, No. 37,237; Kurt N. Jones, No. 37,996; John H. Allie, No. 39,088; Jeffrey A. Michael, No. 37,394; Deborah R. Beck, No. 37,370; Holiday W. Banta, No. 40,311; Troy J. Cole, No. 35,102; L. Scott Paynter, No. 39,797; J. Andrew Lowes, No. 40,706; Darrin Wesley Harris, No. 40,636; Matthew R. Schantz, No. 40,800; Gregory B. Coy, No. 40,967; Lisa A. Hiday, No. 40,036; and John V. Daniluck, No. 40,581.

8444Q

U S APPLICATION NO (if known, see 37 CFR 1 5)	INTERNATIONAL APPLICATION NO PCT/GB95/02535	ATTORNEY'S DOCKET NUMBER 7250-3 (Qin)

17. ☒ The following fees are submitted:	CALCULATIONS PTO USE ONLY	
BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)) :		
Search Report has been prepared by the EPO or JPO $910.00		
International preliminary examination fee paid to USPTO (37 CFR 1.482) $700.00		
No international preliminary examination fee paid to USPTO (37 CFR 1.482) but international search fee paid to USPTO (37 CFR 1.445(a)(2)) $770.00		
Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO $1040.00		
International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(2)-(4) $96.00		
ENTER APPROPRIATE BASIC FEE AMOUNT =	$ 910.00	
Surcharge of **$130.00** for furnishing the oath or declaration later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492(e)).	$ .00	

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	18 - 20 =	0	X $22.00	$ .00	
Independent claims	1 - 3 =	0	X $80.00	$ .00	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ $260.00	$ .00	
TOTAL OF ABOVE CALCULATIONS =				$ 910.00	
Reduction of 1/2 for filing by small entity, if applicable. Verified Small Entity Statement must also by filed (Note 37 CFR 1.9, 1.27, 1.28).				$ 455.00	
SUBTOTAL =				$ 455.00	
Processing fee of **$130.00** for furnishing the English translation later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492(f)). +				$ .00	
TOTAL NATIONAL FEE =				$ 455.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). **$40.00** per property +				$ 40.00	
TOTAL FEES ENCLOSED =				$ 495.00	
				Amount to be: refunded	$
				charged	$

a. ☒ A check in the amount of $ 495.00 to cover the above fees is enclosed.
Along with a check in the amount of $645.00 to cover the fee for filing a Petition For Revival of an Unintentionally Abandoned Application (37CFR 1.17(m))

b. ☐ Please charge my Deposit Account No. _____ in the amount of $_____ to cover the above fees.
A duplicate copy of this sheet is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 23-3030. A duplicate copy of this sheet is enclosed.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO
Thomas Q. Henry, Esq.
WOODARD EMHARDT NAUGHTON MORIARTY & McNETT
111 Monument Circle, Suite 3700
Indianapolis, Indiana 46204
(317) 634-3456

Thomas Henry
SIGNATURE

Thomas Q. Henry
NAME

28,309
REGISTRATION NUMBER